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Michael Leavitt, Administrator
U.S. Environmental Protection Agency
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PETA
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Re: Comments on the API's Test Plan for the Gas Oils Category

Dear Administrator Leavitt:

The following comments on the API's High Production Volume (HPV) test plan for the Gas Oils category are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The API plans to conduct two combined reproductive/developmental tests (OECD 421) and two acute fish toxicity tests on high aromatic and high saturated gas oil streams. These tests are unnecessary and duplicative of previous testing, do not take into account the existing information on these compounds, and violate both EPA and OECD testing guidance. While we have repeatedly objected to API categories that did not encompass similar substances and the API's continued proposal of needless testing in previous test plans, we note in this case that combining these 28 CAS numbers into a single category is preferable to the alternative of smaller categories or to submitting these compounds as individual substances.

We have previously commented on similar plans submitted by the API, noting in particular the continuous nature of petroleum products (Petroleum coke, Lubricating oils, Waxes, Gasoline Category, Petroleum Napthas, Petroleum Gas). The common theme in all these plans is that the primary toxicity of these complex chemical mixtures is generally due to either specific compounds that are already well-characterized (e.g., BTEX or PAH compounds) or to the overall physical properties of the mixture as oily materials. The toxicity of these sorts of materials has been extensively studied both through animal testing and human exposure studies (ATSDR,1995; ATSDR, 1999; McKee et al, 1987; IPCS/WHO, 1982). We have therefore disagreed with the proposed animal testing in all of the API's previous plans.

We must once again repeat our concerns and cite several specific categories that have very similar composition. The API's own Crude Oil Category test plan lays out this argument quite well:

> There is a substantial body of data on products derived from crude oils, such as gasoline, diesel fuels, kerosene and jet fuels, lubricating oils and white oils, which are subjects of other HPV test plans. Extrapolation from these studies provides insight into biologically active components of crude oils. Occurrence and severity of toxic effects appear correlated with concentration of polynuclear aromatic hydrocarbons (PAH) and PAH-containing nitrogen or sulfur heteroatoms (PAC). In addition there are significant data developed from

> monitoring effects of unintentional oil spills, providing "real world" environmental information.

In the specific case of the gas oils, the proposed high-aromatic test stream for reproductive/ developmental testing is very similar in composition to several of the streams in the ACC's Fuel Oil category—a category for which the ACC found enough reproductive and developmental data on these compounds to preclude additional mammalian testing. The proposed high saturate stream contains many similar compounds to those substances contained in the Gasoline Blending Streams, Lubricating Oil Basestocks, and Crude Oil categories. These substances have all been thoroughly studied, are well-characterized including their reproductive and developmental effects, and there is an abundance of human exposure data on them as well. In short, an understanding of the toxicity of these specific compounds and of similar mixtures containing these compounds already exists.

Furthermore, the API is violating both OECD and EPA guidance in proposing to conduct reproductive testing on substances for which it already has repeated dose data that includes an examination of reproductive organs and histopathology as well as developmental toxicity data (all of which appear mostly unremarkable). See p. 17 of the revised test plan, pp. 22-35 and 47-57 of the gas oils robust summary, and pp. 45-51 and 58-60 of the distillate fuels robust summary.

The EPA has clearly stated, for example in its comments on the HPV test plan for gamma-butyrolactone (http://www.epa.gov/chemrtk/gammabut/c14221tc.htm), that an "evaluation of reproduction organs from … repeated-dose toxicity studies adequately address this [reproductive] endpoint." The OECD states in its *Manual for Investigation of HPV Chemicals* that when repeated dose studies which include the effects of reproductive organs and a developmental study are available, "the requirements for the reproduction toxicity endpoint would be satisfied" (Chapter 4).

It is unclear whether the API is unaware of this guidance or simply ignoring it. There is absolutely no reason why a weight-of-evidence analysis of the developmental and repeated dose information cannot be used to meet the reproductive endpoint for the gas oil category. This is a scientifically valid analysis and adequate for a screening level program and is recommended by both the EPA and the OECD. As other HPV sponsors did when following this approach, the API should summarize the repeated dose data, including the histopathology and observations on the reproductive organs in detail, and hence obviate the perceived need to kill another 1,300 animals.

The API's proposed fish toxicity testing is equally uncalled for given that the "experiment" of spilling diesel in fisheries has been conducted thousands of times in the real world. The API acknowledges the abundance of laboratory data that exist for these compounds (p. 22 of the test plan):

> Multiple ecotoxicological studies on heating and transportation fuels (e.g., no. 2 fuel oil and diesel fuel) have been conducted. In general, these commercial distillate fuels show moderate toxicity to aquatic life. LL50 values for fish ranged from 3.2 to 65 mg/L (Exxon, 1998a-c; 1999; Shell, 1995a,b), while EL50 values for invertebrates ranged from 2.0 to 210 mg/L (Exxon, 2001; Fraunhofer, 2000; Shell, 1994, 1995c,d). All studies used exposures to water accommodated

> fractions of the gas oils. No differences in the sensitivity of fish and invertebrates to no. 2 fuel oil or diesel fuel were noted. In contrast, algal EL50 values were consistently lower for no. 2 fuel oil, suggesting a greater sensitivity of algae to no. 2 fuel oil than to diesel fuel. EL50 values for inhibition of algal growth rate and biomass ranged from 1.8 to 2.9 mg/L for no. 2 fuel oil and from 10 to 78 mg/L for diesel fuel (Exxon, 1998d,e; Shell, 1995e,f).

Extensive field experience associated with the large-scale discharge of these or similar substances to both fresh and saltwater systems clearly documents the hazard associated with these compounds. As summarized in the ACC's Fuel Oil Category test plan, the toxicity mechanism is non-polar narcosis, a clearly understood mechanism, and further SIDS testing will not increase the current understanding of potential risks to aquatic systems.[1]

Finally, many of the components of these substances have log K_{ow} values greater than 4.2 (with a cited range of 3.7 to >6 on page 19 of the test plan). **The EPA has clearly stated that acute fish tests are inappropriate for compounds with log $K_{o/w}$ values above 4.2. The EPA recommends that with such highly hydrophobic compounds a chronic *Daphnia* test be used instead of acute fish and *Daphnia* tests (EPA *Federal Register,* December 2000, p. 81695).**

It is appalling that, with this abundance of data, the API is unwilling to adhere to even the first principle for considering animal welfare concerns as outlined in EPA's October 14, 1999 letter to participants:

> In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

We must ask the API, yet again, to undertake a thoughtful analysis of these materials and not condemn approximately 1,500 animals to suffering and death *in direct violation of both EPA and OECD guidance* and in order to retest well-characterized compounds whose risks are already well understood and quantifiable.

[1] The ACC has already documented this mechanism. Its Fuel Oils Category states: "The aquatic toxicity of products in the Fuel Oil Category are expected to fall within a narrow range regardless of the varying carbon number range and constituent composition of those products. This is expected because the constituent chemicals of those products are neutral organic hydrocarbons whose toxic mode of action is non-polar narcosis. The mechanism of short-term toxicity for these chemicals is disruption of biological membrane function (Van Wezel and Opperhuizen, 1995), and the differences between toxicities (i.e., LC/LL50, EC/EL50) can be explained by the differences between the target tissue-partitioning behavior of the individual chemicals (Verbruggen *et al*., 2000). … The existing fish toxicity database for hydrophobic neutral chemicals supports a critical body residue (CBR, the internal concentration that causes mortality) of between approximately 2-8 mmol/kg fish (wet weight) (McCarty and MacKay, 1993; McCarty *et al*., 1991). When normalized to lipid content the CBR is approximately 50 umol/g of lipid for most organisms (Di Toro *et al*., 2000). Because most of the products in this category are composed of complex combinations of relatively similar series of homologous chemicals, their short-term toxicities are expected to fall within the range of toxicity demonstrated by the chemicals and products summarized in this test plan. Therefore, these existing data that are believed to form a sufficiently robust dataset to initially characterize the expected range of aquatic toxicity for products in this category" (http://www.epa.gov/chemrtk/fueloils/c13435rt.pdf, p. 18)

I can be reached at 757-622-7382, ext. 8001, or via e-mail at JessicaS@peta.org should you have any questions.

Sincerely,

Jessica Sandler, MHS
Federal Agency Liaison

Literature cited

ATSDR. (1995). Toxicological Profile For Polycyclic Aromatic Hydrocarbons (PAHs). Prepared By Research Triangle Institute for the U.S. Department Of Health And Human Services. Public Health Service.

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